REMARKS

The claims are 21-33. The non-elected subject matter is canceled without prejudice to applicants' rights thereto.

The original claims have been re-drafted as follows:

Original	New
1,2,7	21
5	22
9	30
10	23-26
19	33

The new claims are supported by the original claims and the specification as follows:

Claim	Page
27	7
28-29	8
31	10
32	6.

The rejection of claims 10 and 11 under 35 USC 112 because of the use of the "trademark" FK106 and because of reference to European patents is mooted by the amendment.

Claims 1, 2, 5, 9, 10, and 17-19 are rejected under 35 USC 102 as anticipated by Orban (US '396). The rejection is traversed. Orban discloses a cyclosporin containing composition for intravenous administration. The present claims are directed solely to oral compositions. Specifically, the invention as presently claimed relates to compositions in the form of hard gelatin capsules. Col.4, example 1 of Orban discloses a composition containing cyclosporin, Solutol HS 15, and ethanol. The solution is homogenized, filtered and has to be diluted prior to application with an isotonic solution. The disadvantage of this preparation is that it has to be administered by trained personnel which includes inconvenience and discomfort for the patients. Moreover, sterility problems may arise. Nowhere in this prior art is evidence that this composition may also be used for oral administration.. There is no teaching or suggestion that this composition may also be advantageous with respect to stability and bioavailability in medicaments for oral administration. Further, claim 19 (now 33) relates to a hard gelatin capsule additionally comprising a mono-, di-, and/or tri-glyceride of a C_{16}-C_{18} fatty acid. Orban discloses none of these compounds. Hence, the invention as presently claimed is novel over Orban.

Claims 1, 2, 5, 7-11, and 17-19 are rejected under 35 USC 102 as anticipated by Hauer (US '625). The rejection is traversed. Hauer discloses a cyclosporin-containing composition in the form of a microemulsion-preconcentrate comprising a hydrophilic

component, a lipophilic component, and a surfactant, e.g. a polyoxyethylene stearic acid ester. The present invention provides hard gelatin capsules comprising a polyethyoxylated saturated hydroxy-fatty acid. Thus, Hauer does not anticipate.

The rejection of claims 17 and 18 is mooted by the amendment.

Claims 1, 2, 5, 7-11, and 17-19 are rejected under 35 USC 103 as obvious over the combination of Hauer (US '625) and Orban (US '396). The rejection is traversed. Because of their hydrophobic character, cyclosporins present highly specific difficulties in relation to administration and the formulation of oral compositions. In particular, it is difficult to produce pharmaceutical compositions showing stability, high biovailability and low intra- and inter-subject variability. When administered intravenously, active agents appear directly in the bloodstream, and are able to immediately produce their pharmacological effect. When administered orally, however, compositions have to enable effective resorption of the active agent from the stomach or gut lumen and achievement of consistent and appropriately high blood/blood-serum levels. It follows, that the effect of orally administering a composition suitable for intravenous application is unpredictable. Further, there is no motivation to use the composition of Orban for oral administration since it has been found to be suitable to avoid anaphylactic side-effects when administered intravenously. Thus, there would not have been any motivation to combine these references or to provide the hard gelatin capsules or of the present invention which may be administered orally, have satisfactory bioavailability, low intra- inter-subject variability and stability. Hence, the present claims are not obvious over the art.

A three-month extension is hereby requested to respond to the Office Action of July 18, 2001. Please charge Deposit Account No. 19-0134 in the name of Novartis Corporation in the amount of $920 for payment of the extension fee. The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.17 which may be required, or credit any overpayment, to Account No. 19-0134.

03/15/2002 VBARLOW 00000001 190134 09738212
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Respectfully submitted,

Novartis Corporation
Patent and Trademark Dept.
564 Morris Avenue
Summit, NJ 07901-1027

Gabriel Lopez
Attorney for Applicants
Reg. No. 28,440
(908) 522-6933

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